MAY 2 2 2002

K020730

Summary of Safety and Effectiveness

Date of Preparation: March 4, 2002

Submitter: Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262

Contact: Earl Draper
Telephone: 714-283-2228

Device Trade Name: **Orion Nasal CPAP System**

Device Common/Classification Name: The Orion Nasal CPAP System is a Bird Products Corporation device classified under 73 BZD, "Non-Continuous Ventilator, per Regulation No. 868.5905.

Predicate Device: The Bird Products Corporation Softaire/Alura Nasal CPAP System

Intended Use: The Orion Nasal CPAP System is intended for treatment of Obstructive Sleep Apnea (OSA). Obstructive Sleep Apnea is defined as the absence of air movement in ten seconds during sleep. Obstructive Sleep Apnea is usually diagnosed through a sleep study. The study obtains the optimum level of pressure required to maintain airway pressure to the obstructed airway. The positive pressure allows the airway to stay open. The Orion Nasal CPAP System is intended only for spontaneously breathing patients.

Device Description: The Orion Nasal CPAP System is intended to provide continuous positive airway pressure for the care and treatment of individuals suffering from obstructive sleep apnea. The positive pressure is clinician-adjustable within the designed operating range, and a clinician-adjustable time allows at timed rise to the set pressure. The user controls are limited to an On/Off switch and the optional pre-set time rise to the set pressure. This device is designed to be used with a 22-millimeter, smooth-bore air delivery hose and user-selected nasal or face mask. The Orion consists of a plastic enclosure that surrounds a power supply, impeller and motor, microprocessor, motor controller, display and switch inputs.

- Power Supply Input Voltage: 90-260 Vac
- Motor & Impeller: Papst 24 Vdc brushless motor
- Microprocessor: 8-bit micro-controller with 8K of program space and 368 bytes of RAM, running at 4.0 mHz.
- Motor Controller: Motorola MC33035 controller for brushless D.C. motor, operating from 10 to 30 Vdc.
- Display: Four-digit display controlled by the microprocessor; digits are multiplexed so that only one digit is on at a time.
- Switch Inputs: There are 5 membrane push-button switches used for input of Mode, Plus and Minus pressure, Rise to Pressure On, and Rise to Pressure Off.

Comparison to Predicate Device: The Orion Nasal CPAP System is not significantly different from the predicate device, the Softaire/Alura Nasal CPAP System as cleared for market under 510(k) 990856.

Summary of Performance Testing: Performance testing was conducted in the laboratory to confirm compliance to device specifications; all functions were verified to operate as designed and intended, and measured parameters met required ranges and accuracies. Testing to internationally accepted standards for electrical safety and electro-magnetic compatibility were performed by a Nationally Recognized Testing Laboratory (NRTL); the Orion complied with the requirements of these standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2002

Mr. Earl Draper
Bird Products Corp.
1100 Bird Center Drive
Palm Springs, CA 92262

Re: K020730
Orion Nasal CPAP System
Regulation Number: 868.5905
Regulation Name: Non-continuous ventilator
Regulatory Class: Class II (two)
Product Code: BZD
Dated: May 7, 2002
Received: May 13, 2002

Dear Mr. Draper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020730

Device Name: Orion Nasal CPAP System

Indications For Use:

The Orion Nasal CPAP System is intended for treatment of Adult Obstructive Sleep Apnea (OSA). Obstructive Sleep Apnea is defined as the absence of air movement for ten seconds during sleep. Obstructive Sleep Apnea is usually diagnosed through a sleep study. The study obtains the optimum level of pressure required to maintain airway pressure to the obstructed airway. The positive pressure allows the airway to stay open. The Orion CPAP System is intended only for spontaneously breathing patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020730

Prescription Use ✓
(Per21 CFR8O1.109)

OR

Over-The-Counter Use _

(Optional Format 1-2-96)